

Rejection under 35 USC §112

Claims 7, and 10 to 14 are rejected under 35 USC §112, first paragraph as containing subject matter which was not described in the specification. Applicants respectfully traverse this rejection.

Applicant is unclear what is issue under 35 USC §112, first paragraph with regards to Claim 7. Claim 7 is an original claim and is clearly described in Example 3b) of the specification. Therefore, as to this claim, further clarification is requested in order to respond further to this rejection.

With regards to Claims 10 to 14 Applicant is clearly confused as to what the Examiners issues are with this process. The claims are narrower than those originally filed, and are supported in the specification. If the production of penciclovir described in Example 3b), page 4, in the specification is not a hydrolysis reaction then the Examiner is asked to clarify just what reaction it is supposed to be. What more support can possibly be expected for claim 7 than the actual example (Example 3b) showing the production of penciclovir using the claimed process

The specification, at the time of filing, is believed to provide sufficient guidance to the skilled artisan on the relevant process steps necessary to make and use the claimed invention. The various process steps as claimed herein are supported by original claim 1 and the examples.

In view of these remarks, reconsideration and withdrawal of the rejection to the claims under §112, first paragraph is respectfully requested.

Rejection under 35 USC §102 (b)

Claims 5 and 15 to 19 are rejected under 35 USC §102(b) as being anticipated by EP 302,644. Applicants respectfully traverse this rejection.

Applicants have cancelled claims 15 to 19 hence removing this reference as to those claims. However, the Examiner also includes in this rejection the compound of Claim 5. This compound is shown in the Geen Annex on page 10, bottom structure.

The EPO 302644 ('644) does not disclose this compound. The process used in the '644 patent remove the chlorine in the 6-position prior to decarboxylation, therefore this compound would not be an intermediate in the '644 process and is not anticipated by the '644 disclosure.

In light of this reconsideration and withdrawal of the rejection to the claims under 35 USC §102(b) is respectfully requested.

Rejection under 35 USC § 103

Claims 5 to 7, and 10 to 20 are rejected by the Examiner under 35 USC §103(a) as being unpatentable over EP 302,644 ('644). Applicant also respectfully traverses this rejection.

The Examiner has referred back specifically to point B from an earlier action concerning reduction conditions. In a comparative synthesis presented in the accompanying Jones Declaration the same reduction conditions were used for the "EP 302644 type process" as for that described in the application under examination, namely reduction of the methyl ester to the corresponding diol using NaBH_4 , in dichloromethane at 20 degrees C. See paragraph 4, Stage 2 step 1 and paragraph 6, Stage 2 step 1 of the Declaration.

The Jones declaration summarizes, in paragraphs 8 and 9, page that the process of the instant application provides for a substantially improved process to produce famciclovir which process retains the 6-chloro substituent during decarboxylation as opposed to the process described in the '644 application.

The bromotriester route, described in EPO 302644, is a process, which has been found to be inconvenient for use on a large, commercial scale. In contrast the present process was developed as an improvement to the bromotriester route in order to facilitate large scale commercialization of the process.

The teachings of the EPO 302644 reference would not lead the skilled artisan to carry out the sequence of steps as presently claimed herein, i.e. coupling, decarboxylation, reduction and esterification, followed finally by removal of the 6-chloro substituent.

The unexpected results achieved by retention of the 6-chloro throughout the claimed process is significant and is further confirmed by the Declaration of Dr. Jones.

These particularly advantageous and unexpected features of the present invention are not taught nor suggested in the '644 application. The skilled artisan would not be motivated by the '644 reference to retain the chlorine in the chemical intermediates. A skilled artisan would not be directed to the improved benefits of yield in the decarboxylation step, nor to the improved yields in the reduction and acetylation steps.

The Examiner's comments re that declaration of Geen is too fragmentary is unclear. Clarification of what is fragmentary is requested in order to further

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prosecution on the merits. It is believed that the Annex clearly shows the steps taken and the comparison of the process conditions.

In light of these remarks and claim amendments, reconsideration and withdrawal of the rejection to the claims under 35 USC §103 is respectfully requested.

Conclusion

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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